EXHIBIT D1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE NO. 2:12-MD-02327 MDL NO. 2327
THIS DOCUMENT RELATES TO ALL WAVE 4 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS:	:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Rebecca Melton CASE NO. 2:12-cv-04094	:	

Transcript of deposition of BRIAN D. PARKER, M.D., taken by Charlene M. Shade, LCR, Notary Public, at the Hilton Garden Inn West, 216 Peregrine Way, Knoxville, Tennessee on Tuesday, March 14, 2017, commencing at 8:30 a.m.

Q. And have you served as an expert before?

A. No.

Q. Have you been involved with Ethicon in any other capacity as a consultant?

A. No.

Q. In looking at your CV, I saw that you may have been involved with another device manufacturer. What other manufacturers have you been involved with consulting?

A. With Galil Medical. They have a cryoablation machine for malignancy. I'm a proctor for Medtronic and for Coloplast. I'm a proctor for their Altis line.

Q. How long have you been a proctor for Coloplast?

A. Well, probably three years, but, honestly, I've only proctored a few times. Yeah, probably about three years.

Q. And how long have you been performing procedures that include vaginal mesh products?

A. Since residency, so that would be somewhere around two thousand and -- no. Let's see. Yeah, probably around 2001, 2002.

Q. Do you recall what the first mesh product was that you were familiar with?

A. The TVT retropubic.

events that you may have treated?

A. Well, I'm not in an academic setting so I really don't have a need -- or it's not the need, but I don't have -- I'm not doing studies on my patients, so I don't have a registry.

Q. That was going to be my next question actually. Have you been involved with any studies or registries with regards to the sling?

A. No.

Q. Doctor, do you also implant POP devices?

A. No.

Q. Doctor, are you familiar with the difference between mechanically-cut versus laser-cut meshes?

A. I am.

Q. Tell me what your understanding is of the difference between those two devices.

A. Well, one is actually physically cut with some type of shears or some type of device, and the other one is cut on the side with a laser to give you the device shape. I don't know anything more than that, though, how they do it.

Q. And have you implanted both types of mesh?

A. I assume I have. I know I have. I know I have because TVT-Secur is laser cut and the TVT-O is, for

the most part, mechanically cut.

Q. Do you recognize any differences between the meshes, the two types of meshes, when you look at them or feel them?

A. I don't notice any differences when I feel them. The only difference you can see is when the laser has come across the edge, there may be more of a heat-sealed type of look on the side of it. But there's no -- other than that, they feel the same, they look the same, yeah. It's not something in residency or in training that has been brought up. But, yeah, I know now.

Q. Are you familiar with the differences in the type of adverse reactions that are associated between the two types of devices?

MR. WALKER: Object to form.

A. No. Honestly, I haven't seen anything like that in the literature. It appears to me that the adverse events are about the same.

Q. Have you ever witnessed in your practice with the meshes that you have implanted that were mechanically cut -- have you ever witnessed any particle loss on those products before you implanted them?

A. Not that I'm aware of.

Q. Were you aware that the mechanically-cut meshes could lose particles or fray?

when you're done. I'm not going to ask you to remember anything you read on it, but just in general ask you some questions when you're done.

THE WITNESS: Here you go.

BY MS. BAGGETT:

Q. And after reviewing that document, would it appear to you that Ethicon was aware, at least as early as 1987, of the potential for their prolene sutures material to degrade?

MR. WALKER: Object to form.

A. The way I'll answer that is prolene has been around for 50 years, has been used in multiple different settings, transplant surgery, cardiovascular surgery, and it continues to be used. It's still on the market. And so whether there's some findings of changes in the mesh or not or on the prolene suture or not, you know, clinically, it really has no -- there's really nothing that I can -- from a clinical standpoint, there's no adverse events that we've been able to determine.

Q. When you were being trained on devices manufactured by Ethicon, you understood that those devices all contained the same type of polypropylene; the TVT, the TVT obturator and TVT-S devices all contained the same type of mesh, which was the prolene mesh, correct?

A. Yes.

Q. And you knew that those were made from the same material that the sutures were made from. Is that accurate?

A. Yes.

Q. And were you aware back at that time of the potential for the sutures to become degraded?

MR. WALKER: Object to form.

A. I disagree with that. I would have to think that something that would be used as a suture for vessels would have to be proven to be non-degradable. And so based on that and the fact that I've seen the mesh after it's been removed and there's no visible change in the mesh, I really can't agree with the initial premise of your question.

Q. I think my question was just simply did you know that the polypropylene had a tendency to degrade after implantation back when you were being trained on the devices.

MR. WALKER: Object to form.

A. Well, are you basing it on that one article?

Q. Well, I'm just asking --

A. Because from a clinical standpoint, we would assume all surgeons are trained to look at prolene suture as a non-degradable suture. So that is the premise

that I came into this with and continue to use, not that -- well, I'll just stop with that.

Q. When was the first time you had heard of the potential of degradation with regard to polypropylene?

A. Not until late last year.

Q. When you began preparing for your report?

A. Yes, ma'am.

Q. I'm going to show you a document that's marked ETH.MESH.00004755, and I'll represent to you that this was another document that was produced in the discovery of this case. And this document is also dated in 1988, and it just has some notes with regard to some explants, and I just want you to look at it and then I'll briefly ask you a question.

A. Okay. You can ask me.

Q. Sure. What does this appear to be to you?

A. These are -- these are explants of something and it describes whether there's cracking or not cracking. I don't -- these are explanted something or other. I don't know exactly what these are.

Do you know what those are?

Q. Well, I don't want to misrepresent anything on the record, but my understanding was polypropylene material that had been explanted.

The next document I'm going to hand you is

there, depends on how open that is, but then also up to the academic guys, yeah.

Q. Are you suggesting with this section that when a manufacturer learns about something good or bad that they should share that information --

MR. WALKER: Object to form.

MS. BAGGETT: -- with the medical community?

THE WITNESS: I think that's something that each individual -- well, I think that's something that each individual company has to decide on their own. And then I think also that it's not necessarily something they have to share with the community, but it's something that needs to be evaluated and looked at and discussed.

I mean, look, there's no perfect procedure for anything and so it always can be improved upon. And that's my point, is if we just said, oh, this is perfect, we never have any issues with anything, then there's never this idea about improving upon what we already have.

BY MS. BAGGETT:

Q. Do you hold any opinions or are you familiar with the FDA review process for getting devices to the market?

A. On the surface, but nothing in detail.

Q. You're not going to hold any opinions here today as to whether or not Ethicon complied with the FDA regulations for marketing their products?

A. I know they went through the proper channels to get the FDA to approve it. From a physician's standpoint, that's really all that I'm concerned about.

Q. What do you base that knowledge on?

A. I'm not sure I understand what you're asking me.

Q. Well, you said the fact that they were approved through the FDA.

A. Well, I guess I'll put it to you simply this way. As a clinician, if I know it's FDA approved, then I feel like that's an adequate way for each individual product to be cleared. And the amount of hurdles it has to go through to pass the FDA is substantial enough that that's their job, that's their role as a regulatory -- you know, I'm not a regulator so I don't know all the rules and regulations. But I do know once it comes to market that, you know, we should feel that the FDA has done their due diligence.

Q. And are you familiar with the difference between having a product cleared versus approved?

A. Yes.

Q. And what is your understanding of that distinction?

A. One has to do with devices and one has to do with medications.

Q. Are you familiar with something called the (510)k process?

A. Through my review of things I have become familiar with it somewhat.

Q. What's your understanding of the difference between the 510(k) process and pre-market approval process?

A. It seems to me the 510(k) process -- and, again, I'm not a regulator so I'm talking off-the-cuff a little bit -- is when another device is already approved, and based on that device they can move the FDA process a little bit quicker in order to -- because there's already been safety and efficacy from the previous product, they can use that as their basis to get another product approved.

Q. So would you agree that that process is a little less intensive for the manufacturer than the full-blown pre-market approval process?

A. Likely, but I have no way of knowing that.

Q. And are you familiar with the process by which the FDA actually scrutinizes the devices before they

are put on the market?

A. I have no inside information on that, ma'am.

Q. You mentioned earlier that the FDA does its due diligence. What did you mean by that?

A. Well, I mean, it's hard to get any product on the market in America versus in a lot of other countries. And so I think that's -- because of that, I mean, the products that come out are generally viewed as being tested of some sort, that they are safe, that they say what they intend to do.

So when they actually come on the market, as physicians we don't have to go through that whole process and review each step of the way. We just have to assume that the FDA has their regulations they meet and once it hits the market that we should feel comfortable with it. I think if each individual clinician had to go back and review the process that it took for each individual product that comes to market, that would be too onerous. There's no need for that, so...

Q. And you agree that that's the way it should be, that in order for a product to make it through that process, that the proper studies had been done and that there was some showing that the product was indeed safe and effective?

MR. WALKER: Object to form.

A. I think that the FDA has decided, in many years, that there are certain processes to go through, and I can't disagree with FDA's approval process.

Q. Are you here today offering any opinions on whether or not Ethicon complied with all the FDA regulations with regards to the studies and the data in order to get the products brought to market?

MR. WALKER: Object to form.

A. The FDA approves the products. They're on the market so I have to assume that that was adequate for the FDA. Again, I'm not a regulator; I'm just a clinician.

Q. And that's what I'm trying to get at. Are you going to be offering any opinions with regard to that process and whether or not Ethicon complied with that process?

A. I'm not a regulator so I can't comment on the regulations that go along with that.

Q. So, no, you won't be?

A. No.

Q. Thank you.

MR. WALKER: Can we take five minutes?

MS. BAGGETT: Sure.

(Thereupon a break was taken from 10:39 a.m. to 10:45 a.m.)

weren't sterilized and reused. So each kit had an individual trocar.

Q. And other than the sling -- and I know you said you don't do POP procedures, but other than those type procedures, is a trocar something you use in your normal practice in any other procedures?

A. Yes.

Q. What type of procedures?

A. Interstim, and there's a trocar that passes the wire or the lead underneath the skin from the sacrum over to the battery site.

Q. Is that something that's supplied with the Interstim device as well?

A. Yes.

Q. Now, do you train others how to implant these devices?

A. I do.

Q. And by that I meant the TVT devices, the TVT-Secur, the TVT retropubic.

A. No, I do not.

Q. Are you holding any opinions here today as to whether or not Ethicon's training materials and professional education were adequate with regard to the TVT-O and the TVT-S devices that we're here today about?

A. Yes.

Q. And what are those opinions?

A. They were adequate.

Q. And did you review all of the materials, the professional education materials, within Ethicon in formulating that opinion?

A. That's part of it, yes, ma'am.

Q. Did you also review internal materials with regards to the development of the procedure as it was laid out in the IFU?

A. I'm not sure I'm following on that. Because what I thought you were meaning was as a surgeon operating on a patient, do you rely on the professional handouts. And so for that I agree. But as a clinician and a surgeon, you wouldn't have privy to those other documents. If you're asking as an expert witness if I'm relying on those things, that's different than just me being a surgeon and operating.

Q. I guess that's where I was going with that. Are you holding any opinions today with regards to the materials that were used to train doctors as to whether that information, those materials, were adequate in this case?

A. Yes.

Q. You do have opinions, and that's based off of --

A. That's based off everything I saw.

Q. So that would include the materials, the internal Ethicon documents --

A. Uh-huh.

Q. -- and all the training materials associated with the device?

A. Yes, ma'am.

Q. And you've read all of them?

A. I think so, but I couldn't -- I don't know that I've seen every one of them, but all the ones that I saw I think I looked at and read.

Q. And have you heard of -- have you seen what is referred to as a cookbook with regards to the TVT-S?

A. Cookbook?

Q. In the materials you reviewed, did anything --

A. Well, maybe it's the same thing I'm thinking of. But it was kind of like there are like Tips & Tricks? Yeah, I do remember seeing that.

Q. Do you recall whether or not the Tips & Tricks were similar to the instructions that were included in the original IFU, the instructions for use?

A. I believe the Tips & Tricks came out later to help speed up the learning curve.

the body, the more the body is going to have to respond to address that foreign body. Would you agree with that?

A. I agree that the larger surface area, there's more contact with the tissue, but the actual amount of reaction doesn't increase in that specific spot for that particular piece of mesh or prolene or whatever foreign body we're talking about.

Q. And with regards to the -- you were discussing the difference in mesh weaves and the size. Do you have any understanding of how the porosity of a device affects the surface area that comes in contact with the body?

A. Yes.

Q. What is that understanding?

A. That anything bigger than 75 microns is a large enough pore size to allow ingrowth of fibroblast and macrophages and the normal healing that you'd see.

Q. Have you reviewed materials with regards to the pore size in the devices we're talking about today?

A. Yes.

Q. What materials did you review to get your understanding of the pore size in the TVT-R, the TVT-O and the TVT-S devices?

A. I don't remember the name of the document. I don't recall the name, but I know I looked at it multiple

times.

Q. What is your understanding of the porosity of the TVT-R, the TVT-O and the TVT-S devices?

A. Those are all 1.37 microns; 1,379 microns. I'm sorry.

Q. Are you familiar with the term "effective porosity"?

A. Not specifically.

Q. Do you -- in your experience with the meshes that you've implanted, you understand that the mesh is flexible, correct?

A. I agree.

Q. And that it stretches. It's elastic in some aspects. Is that true?

A. It is.

Q. Do you have an understanding of whether or not stretching the material changes the porosity?

A. If I took the mesh and I pulled it like this, would it change the form, the size of the pores?

Q. Yes, sir.

A. I would expect so.

Q. Do you have an understanding of whether or not the mesh -- once it has been stretched or put under tension, whether or not the mesh regains the original pore size or if it remains collapsed?

MR. WALKER: Object to form.

A. I don't know specifically, but I would think if it hits a certain threshold, it would probably not regain its form.

Q. Would that be important with regard to tissue ingrowth once the device is implanted?

A. No.

Q. It would not?

A. The reason being, is there is no physiologic force that can stretch that material in a way that it can't be -- there's no force that can stretch that material that it would change the pore size of any significance.

Q. Do you agree that when the mesh is placed initially in the body that the woman is usually in a position where she is laying down to where there's no tension on the mesh with regards to the organs that it's supporting, the lithotomy position?

A. The lithotomy position. That's the normal position to place it, yeah.

Q. Does the tension that is placed on the mesh change when the woman stands up?

A. Ever so slightly.

Q. And by "ever so slightly," do you have an understanding of how much it changes?

A. No, I do not have like a number of newtons of cavity that pulls on there. I do know that it's nothing that would be significant enough to change the size of the mesh, because the mesh itself when removed has no real changes in its visible properties.

Q. And that's your understanding, that the mesh pores remain constant after insertion?

MR. WALKER: Object to form.

A. I think the pores can change minimally, but nothing of any substance. And that's due to mainly, probably, from the actual healing process itself. You know, once the healing process starts, then you see probably a -- you know, it gets to a certain point and it's not going to change at all.

Q. But before the healing process starts, do you have an understanding of whether or not the mere fact that a woman standing up or having a body function and putting tension on the mesh, if that has any effect on the porosity before the tissue has a chance to get incorporated into the mesh?

MR. WALKER: Object to form.

A. It's my understanding that that's not enough physiologic force to change any -- have any long-term change in the mesh.

Q. And you said earlier the prolene mesh --

do you know what the different categories of porosity are with regard to the mesh devices? Have you heard of the term "microporous"?

A. Yes. I've seen studies on type I, II, III, and IV mesh.

Q. And which category do you put the prolene mesh that's used in the devices we're talking about today? Which category does that fall under?

A. I believe that's type I, macroporous mesh.

Q. And do you have an understanding of whether or not the mesh used in the prolene mesh -- do you have an understanding of whether or not the prolene mesh that's used in the devices we're here to talk about today, whether or not that is considered heavyweight or lightweight mesh?

A. Well, describe heavyweight and lightweight to me. I think the weight is dependent upon how you're placing it, how you're utilizing that within the body. So I think the definitions I've seen, different definitions, I don't think there's a consensus on that. I think that's kind of a -- I can't find literature that would say this is a consensus, heavyweight, lightweight. But in reality, the amount of weight is pretty minimal when you're actually placing it underneath the urethra. I really can't comment on heavyweight and lightweight. My suspicion is that it's

the appropriate weight.

Q. Are you aware of any concerns, either through the literature or within the medical community, that the heavier weight meshes, the more complications you see? Are you aware of anything like that, or the difference between a macroporous versus a microporous mesh and the outcomes?

MR. WALKER: Object to form.

A. I think you're asking me two different things, because a macroporous mesh and a microporous mesh, I think there's studies on there as far as how the patient heals. As far as heavyweight and lightweight mesh, that's more of an arbitrary discussion and, again, one that I think falls short when it talks about midurethral slings.

I think that's helpful maybe when you're talking about hernia repairs or big pieces of mesh that are placed, but when we're talking about such a small area -- and I've done the math on it. I looked at all the different slings and tried to figure what actual weight you're actually seeing when you place it under the midurethra, and there's very significant little difference. I mean, there's miniscule, you know, micrograms of difference when you actually get that piece of mesh and determine the weight and then the length of all the different ones.

So I'm not -- it's not the heaviest weight, it's not the lightest weight, but it's the appropriate weight to do what it does.

Q. Are you familiar with internal documents within Ethicon that discuss the need for a lighter weight, larger pore mesh?

MR. WALKER: Object to form.

A. Uh-huh.

Q. And are you familiar with the devices that were developed -- or excuse me -- the mesh material that was developed in an attempt to obtain a lighter weight, larger pore mesh for use in the application similar to the devices we're here to talk about today?

MR. WALKER: Object to form.

A. I've seen documents on different types of meshes used from internal documents from Ethicon.

Q. And if there were studies that suggest that a lighter weight, larger pore mesh resulted in safer and better outcomes, would you expect the company to use that mesh if it's available to them?

MR. WALKER: Object to form.

A. Well, you're asking me a hypothetical question, correct? Because that device doesn't exist, or that mesh, that I'm aware of, doesn't exist. So any studies on that would have to be done in the same exact way

that the TVT retropubic or TVT-O or TVT-Secur was done in order to get results that are comparable. And I don't know those.

Q. Are you familiar with the pelvic organ prolapse devices that were manufactured by Ethicon?

A. I know they exist, and that's about the end of my knowledge.

Q. So you're not aware of what type of mesh is used in those products versus the stress urinary incontinence device?

A. I think along the way somewhere I may have heard there's a different mesh, but I don't know a lot of the details because I never implanted those.

Q. So if the mesh that was used in the pelvic organ prolapse devices was lighter weight and larger pore, would you expect the mesh being used in all of their products to be changed in order to obtain the best possible outcomes for their patients?

MR. WALKER: Object to form.

A. I think that's an assumption that you're saying that that same mesh would provide the same function and efficacy when used for a sling. So I don't know that, again, you can compare the mesh for that product versus the mesh for a sling product unless you had, you know, countless number of patients to compare it. I mean, just

because it does the job for one particular problem, I don't think you can just assume it's going to be effective in the same -- for a sling.

Q. Would that also be true with regards to the use of hernia mesh in the abdomen versus hernia mesh in the pelvis?

A. Yeah, that's the same thing. Until you get studies that show it's effective and safe, then I think you should always, you know, make sure you're wary of any type of crossover utilization of products.

Q. In the section on page 8 under Tension-Free Vaginal Tape, the second paragraph, mid paragraph, you talk about prolene sutures being composed of polypropylene. They contain antioxidants to prevent the polymer degradation.

In that section, are you saying that you have an understanding as to whether or not polypropylene can degrade?

A. I don't know all the details of why the antioxidants are put in there. I think that, you know, as we discussed earlier, there's nothing that proves that prolene dissolves. Could there be some things that can help it stay sturdier and stronger? Possibly the antioxidants. Again, I'm not a biochemist so I don't know the details of that. But I'm assuming it would just be

something to help continue to keep its strength.

Q. Are you planning to offer any opinions in this case with regards to whether or not polypropylene used in the prolene devices that make up the products we're here to talk about today, whether or not that polypropylene degrades?

MR. WALKER: Object to form.

A. My opinion is that the prolene does not degrade. And so if you're asking me if I have an opinion about it, yes, I do. That's my opinion. If you're asking me from a biochemist's standpoint what occurs at the cellular level, molecular level, I can't tell you all that. I can just tell you from a clinician, having used prolene suture for many years, doing transplants and other things, that later, when we go back, the prolene mesh is still there. If it wasn't still there, there would be a lot of problems with the prolene -- I mean, the prolene suture, not the mesh -- but the prolene suture would be off the market. So in my estimation, there's no sign of any degradation of or loss of structure of the prolene sutures.

Q. So based on that, is it fair to say that you will be basing your opinions off of your experience with the device rather than your understanding of the science behind the concept; is that correct?

MR. WALKER: Object to form.

A. Can you be more specific how you ask that question? Are you asking me from a biochemical standpoint am I able to give you the composition of the prolene mesh? If you're asking me that, I can say I'm not here to comment on that. If you're asking me to say when that prolene mesh is outused in patients, what happens to it, does it degrade or not, I can certainly answer that without any hesitation.

Q. I guess that's what I'm getting at. Have you reviewed anything in your preparation to draft a report in this case that gave you an understanding from a polymer standpoint whether or not the polypropylene used in this device is appropriate in this application?

A. I can't comment from a biochemist's standpoint, so I will not provide any insight as far as how this thing is put together; only from a clinical standpoint.

Q. In the section on page 9 under TVT Complications and Side Effects, you talk again about the literature and reviewing it to determine the risks and complications associated with all mesh procedures, and you've listed a couple of studies in this section. Specifically with regard to your discussion on dyspareunia, you suggest that "It's a well-known complication that can follow any vaginal surgery whether mesh is used or not. It is also prevalent among women, especially those that are